IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA Alexandria Division

ARIAD PHARMACEUTICALS, INC.,)	
Plaintiff,)	
)	
v.)	Case No. 1:17-cv-733
)	
JOSEPH MATAL,)	
Defendant.)	
)	

MEMORANDUM OPINION

This is an appeal from a decision by the United States Patent & Trademark Office ("PTO"), calculating the patent term adjustment for United States Patent No. 8,114,874 (the "'874 Patent"), owned by plaintiff ARIAD Pharmaceuticals ("ARIAD"). Specifically, the PTO determined that the three month period, beginning with the PTO's erroneous conclusion that ARIAD had abandoned its patent application and ending when the PTO rescinded the notice of abandonment, constituted "time consumed by continued examination" pursuant to 35 U.S.C. § 154(b)(1)(B). Accordingly, the PTO excluded this four-month period from the patent term adjustment calculation. ARIAD argues that the PTO erred in excluding this four-month time period from its adjustment calculation because the continued examination had not yet commenced. This dispute has been fully briefed and argued and is now ripe for disposition.

I.

Congress in the past quarter century has significantly altered the patent law landscape in a manner particularly pertinent to this appeal. Thus, a brief description of this new landscape provides useful context and aids the analysis.

The patent process begins when an applicant seeking a United States patent files an application with the PTO. See 35 U.S.C. § 111. The PTO then conducts an examination of that application, reviewing the application first for procedural requirements and then referring the application to an examiner to determine whether the invention meets substantive patentability requirements. Id. §§ 101, 112, 103, 131. If the examiner determines the application does not meet patentability requirements and issues a final rejection, the applicant may file a request for continued examination ("RCE") of the application pursuant to 35 U.S.C. § 132(b). See 37 C.F.R. § 1.114. When an RCE is filed, the "Technology Center" assigned to the application initially processes the request and verifies that all the threshold requirements for continued examination are satisfied. See Manual of Patent Examining Procedure ("MPEP") § 706.07(h). If the requirements are not satisfied, the applicant is notified and afforded the opportunity to enter amendments. Id. Once the requirements are satisfied, the PTO will withdraw the finality of the preceding rejection and forward the RCE to the patent examiner for review. See 37 C.F.R. § 1.114(d).

If, at the end of this process, a patent issues, the patent term will last for twenty years from the date the initial patent application was filed. Prior to 1994, patent terms were seventeen years from the date the patent issued. In 1994, Congress changed the patent term to twenty years from the date the application was first filed. In changing the start date of the patent term to the date when the application was first filed, Congress noted that PTO delays in the processing of applications would now consume some portion of the patent term. Accordingly, to account for these delays, Congress passed the American Inventors Protection ("AIPA") of 1999, requiring the PTO to grant several patent term adjustments based on delays in the application processing attributable to the PTO. See 35 U.S.C. § 154(b). Specifically, there are three types of delays for

which patentees are entitled to term adjustments: "A Delay;" "B Delay;" and "C Delay." "A Delay" extends the patent term one day for each day the PTO fails to meet prescribed deadlines for certain events during the processing and prosecution of the patent application, including deadlines for mailing notices of allowance, responding to replies under § 132, and issuing the patent after payment of the required fees. See 35 U.S.C. § 154(b)(1)(A). "B Delay" provides a guarantee of no more than three-years of application pendency from the time the application is filed to issuance of the patent. Id. § 154(b)(1)(B). "C Delay" extends the patent term one day for each day of the pendency of an interference proceeding, a secrecy order, or successful appellate review by the Board, or a Federal court. Id. § 154(b)(1)(C). Most relevant to this case is the PTO's calculation of "B Delay." As described above, "B Delay" accounts for delays "due to the failure of the [PTO] to issue a patent within [three] years after the actual filing date of the application . . . " Id. § 154(b)(1)(B). The statute excludes certain time periods from the calculation of that three-year period of time, including "any time consumed by continued examination of the application requested by the applicant under section 132(b)." Id. § 154(b)(1)(B)(i).

In addition to establishing these categories of delay, the statute delegates to the PTO Director the authority to "prescribe regulations establishing procedures for the application for and determination of patent term adjustments" *Id.* § 154(b)(3)(A). Pursuant to this authority, the PTO promulgated a rule calculating the "time consumed by continued examination requested by the applicant" in 35 U.S.C. § 154(b)(1)(B)(i) to include:

⁽¹⁾ The number of days, if any, in the period beginning on the date on which any request for continued examination of the application under 35 U.S.C. 132(b) was filed and ending on the date of mailing of the notice of allowance under 35 U.S.C. 151;

37 C.F.R. § 1.703(b)(1). At the same time, the PTO promulgated a regulation enabling the Director to suspend or waive "[i]n an extraordinary situation, when justice requires, any requirement of the regulations in this part which is not a requirement of the statutes" 37 C.F.R. § 1.183.

Π .¹

Plaintiff in this case, ARIAD Pharmaceuticals ("ARIAD"), is a Delaware corporation and the owner of the United States Patent No. 8,114,874 (the "874 Patent"), relating to an invention designed to treat abnormal protein kinase activity. ARIAD filed the application that culminated in the issuance of the '894 patent on December 22, 2006, ARIAD filed United States patent application number 11/644,849 ("'849 Application"), the patent application for what would become the '874 Patent. After reviewing the application, on August 3, 2009, the PTO sent ARIAD a final Office action rejecting the '849 Application. Thereafter, on February 3, 2010, ARIAD filed a timely request for continued examination pursuant to 35 U.S.C. § 132(b), along with the required fee. PTO received the request for examination on February 12, 2010 but failed to process the request at the time it was received. Instead, one week later—on February 19, 2010—the PTO sent ARIAD a notice of abandonment in error, suggesting that because the PTO had not received a response from ARIAD, ARIAD had abandoned its application. ARIAD subsequently filed a petition to withdraw the notice of abandonment on February 25, 2010, arguing that ARIAD had, in fact, timely filed a request for continued examination. Three months later, on May 13, 2010, the PTO granted ARIAD's request and withdrew the notice of abandonment. Specifically, the PTO concluded the notice of abandonment was issued in error because a "review of Office records reveal[ed] that the Office received the reply on February 12,

¹ These facts are drawn from the Administrative Record. There are no disputed facts at issue.

2010." Administrative Record 418 (Petition Decision (05-13-10)). The PTO also stated in the decision withdrawing the notice of abandonment that the application "will be referred to Technology Center Art Unit 1624 for processing of the reply, and for continued examination in the normal course of business." *Id.* at 419 (Petition Decision 05-13-19). Accordingly, on June 10, 2010, the PTO issued a notice of rescinded abandonment, entered the RCE, and forwarded the application to an examiner. *Id.* at 3 (PTA summary document of ARIAD's '849 Application).

The PTO subsequently mailed a notice of allowance on October 13, 2011, and issued the "'874 Patent" on February 14, 2012 with a calculated patent term adjustment of 0 days under 35 U.S. § 154(b). In 2014, the Federal Circuit held that "time consumed by continued examination" does not include time between the notice of allowance and issuance. *Novartis v. Lee*, 740 F.3d 593, 602 (Fed. Cir. 2014). Accordingly, the PTO recalculated the period of "B Delay" to exclude the time from the filing of the RCE until the notice of allowance, not the time from the filing of the RCE until issuance of the patent. Despite this recalculation, the PTO again concluded that the patent term adjustment was 0 days. Specifically, the PTO determined that the time consumed by continued examination was 609 days, beginning on February 12, 2010 when ARIAD filed its RCE and ending on October 13, 2011 when the PTO mailed the notice of allowance. Accordingly, the PTO excluded that time from the "B Delay" calculation, which yielded a total "B Delay" of 175 days.² In other words, the PTO determined that "time consumed by continued examination" included time when the PTO erroneously considered the patent application to be abandoned. The PTO also added 203 days of "A Delay" for the time

_

² The PTO arrived at that conclusion based on the following calculation: 1881 days (time between the patent application filing date and patent issuance) minus 609 days ("time consumed by continued examination") minus 1097 days (time between the patent application filing date and three years after filing date).

beyond four months that it took the PTO to respond to ARIAD's request for continued examination, resulting in a total "A" and "B" delay of 378 days. Because the PTO determined the amount of delay attributable to the applicant was 463 days, the PTO determined that the amount of "A," "B," and "C" delay did not exceed the number of days attributable to applicant delay and awarded 0 days of adjustment to the patent.

ARIAD subsequently sought reconsideration of this "B Delay" calculation, and on March 9, 2017, the PTO upheld its decision reasoning that the applicant was not entitled to "B Delay" during the pendency of an RCE. After exhausting its administrative appeals, ARIAD filed the instant action on June 26, 2017, pursuant to 35 U.S.C. § 154 and the Administrative Procedure Act ("APA"), contending that the PTO's calculation of ARIAD's "B Delay" was based on an improper construction of the statute. Specifically, ARIAD alleges that the total "B Delay" should be 293 days, not 175 days, and accordingly, that ARIAD should receive a patent term adjustment of 33 days, not 0 days.

The PTO contends that "time consumed by continued examination" includes any time after the filing of an RCE, which occurred in February 2010, and as such, the time from February to June was properly excluded. ARIAD counters by arguing that time during which the PTO erroneously considered the application abandoned and therefore did not conduct continued examination should not be excluded and that this time should be credited to ARIAD as "B Delay."

III.

The standard of review on motions for summary judgment is too well-settled to warrant extensive discussion. Under Rule 56, Fed. R. Civ. P., summary judgment is appropriate only

where there is "no genuine dispute as to any material fact" such that the moving party "is entitled to judgment as a matter of law." *Celotex v. Catrett*, 477 U.S. 317, 322 (1986). A genuine dispute exists if "there is sufficient evidence on which a reasonable jury could return a verdict in favor of the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Where, as here, judicial review is limited to the Administrative Record and the parties agree that no genuine issues of material fact exist, the Court need only decide the relevant legal questions presented by the suit to resolve a case on summary judgment. *See Wyeth v. Kappos*, 591 F.3d 1364, 1 369 (Fed. Cir. 2010).

IV.

The central dispute in this case is whether the PTO's exclusion of time during which the PTO erroneously considered ARIAD's application to be abandoned comports with the statutory requirement that "B Delay" should exclude only "time consumed by continued examination." 35 U.S.C. § 154(b)(1)(B)(i). Analysis of this question properly begins with the statutory text, which provides, in relevant part, that a patent holder is entitled to an adjusted patent term "if the issue of an original patent is delayed due to the failure of the [PTO] to issue a patent within 3 years after the actual filing date of the application," not including "any time consumed by continued examination of the application requested by the applicant." *Id.* The plain meaning of this statutory text is inconsistent with the PTO's interpretation of the statute as applied here. To begin with, it is important to note that Congress did not use the phrase—"time after the applicant filed a request for continued examination" or "time attributable to a request for continued examination" in the statutory text. Instead, Congress chose to draft the provision as "any time consumed by continued examination of the application requested by the applicant." 35 U.S.C. § 154(b)(1)(B)(i). Thus, to read meaning into the language Congress chose requires consideration

of "time *consumed by* continued examination" and not simply any time after a request for continued examination is filed. *See Conn. Nat'l Bank v. Germain*, 503 U.S. 249, 253-54 (1992) ("[C]ourts must presume that a legislature says in a statute what it means and means in a statute what it says it there."). The ordinary meaning of "consumed by" is "used in the course of." Time cannot possibly be used in the course of continued examination where, as here, the PTO erroneously determines the application is abandoned and does not believe it has even received an RCE. Put another way, time cannot be consumed by or used in the course of continued examination where the PTO does not even know that continued examination has been requested. Accordingly, the PTO's exclusion of time when the PTO erroneously considered an application abandoned from ARIAD's "B Delay" calculation is inconsistent with the plain text of the statute.

But this inquiry does not end with the text of this provision, as the Supreme Court has recognized that the plain meaning of a provision "is often clarified by the remainder of the statutory scheme . . . because only one of the permissible meanings produces a substantive effect that is compatible with the rest of the law." *King v. Burwell*, 135 S. Ct. 2480, 2492-93 (2015) (citing *United Sav. Ass'n of Tex. v. Timbers of Inwood Forest Assocs., Ltd.*, 484 U.S. 365, 371 (1988)). Accordingly, it is appropriate to examine the statutory scheme to determine whether Congress intended to include the time when the PTO erroneously concluded the application was abandoned in the patent term adjustment.

The statutory scheme in this case further buttresses the conclusion reached from the plain text of the statute. Section 154(b)(1)(B) uses the same phrase, "time consumed by," in other provisions, namely the statute also excludes from "B Delay" "time consumed by" secrecy orders, appellate review, and proceedings pursuant to § 135(a). *See* 35 U.S.C. § 154(b)(1)(B)(ii). The

8

.

³ Webster's Collegiate Dictionary (11th ed).

regulations interpreting these provisions have made clear that the calculation of the "time consumed by" begins when the event at issue actually occurs—i.e., the imposition of the order, the beginning of the § 135(a) proceeding, or when the appellate court gains jurisdiction.⁴ This same principle, applied here, suggests that the clock for "time consumed by continued examination" should start when the continued examination requested actually begins, and continued examination plainly cannot begin before the PTO acknowledges that it has even received a request and instead considers the application abandoned.

Case law interpreting this provision and other, similar provisions also supports ARIAD's interpretation of the text. The Federal Circuit, in *Novartis v. Lee*, 740 F.3d 593 (Fed. Cir. 2014), addressed this very statutory provision. The question in that case was whether "time consumed by continued examination requested by the applicant" includes time between allowance and issuance of the patent. The Federal Circuit rejected the argument that "continued examination" included time after allowance, noting that "[t]he common-sense understanding of 'time consumed by continued examination,' is time up to allowance, but not later, unless examination on the merits resumes." *Id.* at 602 (internal citations omitted). Importantly, the *Novartis* court recognized that "time from allowance to issuance undisputedly would count toward the PTO's three-year allotment in a case not involving a continued examination" and there was "no basis for distinguishing a continued-examination case." *Id.* at 602. Analogously here, a time period in which the PTO erroneously concludes that an application is abandoned would count toward the PTO's three-year allotment in a case not involving a continued examination and there is no

⁴ See 37 C.F.R. § 1.703(b)(2) (exempting the "number of days, if any, in the period beginning on the date an interference or derivation proceeding was instituted to involve the application . . . and ending on the date that the interference or derivation proceeding was terminated with respect to the application" (emphasis added)); *id.* 1.703(b)(3) ("The number of days, if any, the application was maintained in a sealed condition under 35 U.S.C. 181."); *id.* § 1.703(b)(4) (exempting the "number of days, if any, in the period beginning on the date on which jurisdiction over the application passes to the Patent Trial and Appeal Board under § 41.35(a) of this chapter and ending on the date that jurisdiction by the Patent Trial and Appeal Board ends under § 41.35(b) of this chapter").

statutory basis for distinguishing a continued-examination case. Accordingly, the Federal Circuit's interpretation of this statute points persuasively to the conclusion that PTO's exclusion from B-Delay of time when the PTO erroneously considered an application abandoned is inconsistent with the statute.⁵

ARIAD's interpretation of the statute also comports with the purpose of this statutory provision. The legislative history of the AIPA suggests that Congress intended the "B Delay" exclusions to include delay attributable to the applicant, and not to the PTO. *See* H.R. Rep. 106-464, Conference Report on H.R. 1554, Intellectual Property and Communications Omnibus Reform Act of 1999, printed in 145 Cong. Rec. H29238, 29273 (daily ed. Nov. 9, 1999) (stating that "[a]ny periods of time—(1) consumed in the continued examination of the application under \$132(b) of the Patent Act as added by section 4403 of this Act ... shall not be considered a delay by the USPTO and shall not be counted for purposes of determining whether the patent issued within three years from the actual filing date."). The delay here was indisputably attributable to the PTO; the delay was not the result of the applicant's request for continued examination but rather the delay in question was the result of the PTO's erroneous notice of abandonment.

The PTO's arguments to the contrary are unpersuasive. To begin with, the PTO argues that its interpretation comports with the structure of § 154(b)(1) as a whole because the statute's "A Delay" provisions serve the purpose ARIAD seeks to read into the "B Delay" provisions,

•

⁵ Indeed, even the district court cases the PTO cites support this interpretation of the statute. PTO cites *Maas v. Lee*, 189 F. Supp. 3d 581 (E.D. Va. 2016), for its statement that "a patent applicant will not receive any PTA credit for delay attributable to a request for continued examination." *Id.* at 583-84. But this proposition is consistent with the interpretation of the statute advanced here. Delay accruing after the PTO acknowledges receipt of a request for continued reexamination would be attributable to that request. But the time period before the PTO even knows it has received a request for continued reexamination clearly cannot be attributable to a request for continued examination.

⁶ See also Novartis, 730 F.3d at 601 ("The evident policy behind the three enumerated exclusions is that certain delays are not attributable to the PTO—delays not 'due to the failure of' the PTO to move the process along, § 154(b)(1)(B)—and so should not count against the three years before adjustments begin.")

namely acting as a backstop on delay attributed to the PTO during the continued examination of an application. To be sure, "statutes should be read so far as possible to give independent effect to all their provisions." Babbitt v. Sweet Home Chapter of Comtys. for a Greater Or., 515 U.S. 687, 724 (1995) (Scalia, J., dissenting) (citing Ratzlaf v. United States, 510 U.S. 135, 140-41 (1994)). Thus, ordinarily, an interpretation of a statutory provision that achieves a purpose or result already achieved by a different provision would be disfavored. But, this statute expressly acknowledges and accounts for the potential overlap between "A Delay" and "B Delay." Specifically, § 154(b)(2)(A) provides that "[t]o the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." Rather than suggesting that Congress intended A and B Delays to serve mutually exclusive purposes, this provision shows that Congress explicitly acknowledged that those purposes might overlap and designed a solution to deal with that overlap, namely ensuring that the patent term adjustment does not exceed the days actually delayed, not reading away the plain text of the statute. Indeed, the Federal Circuit has explicitly rejected the PTO's attempts to avoid double counting A and B Delays even where one delay causes the other, noting that "the law has put a policy in effect that this court must enforce, not criticize or correct." Wyeth v. Kappos, 591 F.3d 1364, 1370 (Fed. Cir. 2010).

The PTO's argument that any other construction of the statute would lead to absurd results fares no better. Specifically, the PTO contends that ARIAD's reading of the statute would (i) force patent examiners to parse out precise days when they actually engaged in examination of the application to calculate a patent term adjustment; and (ii) give applicants who initially file non-compliant RCEs an adjustment for the time spent fixing their RCE while

depriving more diligent applicants of a comparable adjustment. To be sure "absurd results are to be avoided," but the plain language of the statute successfully avoids this parade of horribles the PTO predicts. If, as the statute suggests, "time consumed by continued examination" begins when the RCE is forwarded to the patent examiner, the PTO would not need to determine which days the patent examiner actually engaged in continued examination because the clock would begin to run as soon as the request was forwarded. Similarly, the statute accounts elsewhere for any delay caused by non-diligent applicants in revising their RCEs by reducing any period of adjustment of the term of a patent "by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." 35 U.S.C. § 154(b)(2)(C)(i). In sum, the PTO's fears are unfounded because the statutory text ensures that administration of the statute is not overly complex and provides mechanisms for penalizing non-diligent applicants.

Finally, the PTO argues that its interpretation of the statute is entitled to deference. But it is well-settled that where, as here, an agency's interpretation is contrary to the plain language of an unambiguous statute, no deference is afforded to that interpretation. *Smith v. City of Jackson*, 544 U.S. 228, 267 (2005). Because Congress's intent here is clear, "that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *City of Arlington v. FCC*, 569 U.S. 290, 296 (2013) (internal citations omitted).

Even assuming, *arguendo*, that the statutory text is ambiguous, the PTO is still not entitled to *Chevron* deference. The Federal Circuit has recognized that "[b]ecause Congress has not vested the Commissioner with any general substantive rulemaking power, ... the rule of controlling deference set forth in Chevron does not apply" to most PTO regulations, which are

⁷ United States v. Turkette, 452 U.S. 576, 580 (1981) (citing Trans Alaska Pipeline Rate Cases, 436 U.S. 631, 643 (1978); Comm'r v. Brown, 380 U.S. 563, 571 (1965)).

procedural in nature." *Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1550 (Fed. Cir. 1996). This is the case here; the PTO promulgated the rule at issue here pursuant to 35 U.S.C. § 154(3)(A), which gives the PTO Director the authority to "prescribe regulations establishing procedures for the application for and determination of patent term adjustments under this subsection." 35 U.S.C. § 154(3)(A) (emphasis added). Accordingly, because the grant of authority was procedural, not substantive, the PTO's regulations are inconsistent with that rulemaking authority to the extent the regulations make substantive adjustments to the PTA and the patent term. The PTO argues that *Cuozzo Speed Technologies LLC v. Lee*, 146 S. Ct. 2131 (2016), changed this conclusion, but that case is clearly distinguishable. That case involved a much broader grant of rulemaking authority to promulgate regulations "establishing and governing the inter partes review" process. *Id.* at 2136 (quoting 35 U.S.C. § 316(a)(4)). Here, by contrast, the rulemaking authority is expressly limited to developing "procedures" for the determination of patent term adjustments. 35 U.S.C. § 154(3)(A).

V.

In sum, the statutory text, the statutory scheme, case law interpreting this provision, and the purpose of the statute all point persuasively to the conclusion that the PTO's construction of 35 U.S.C. § 154(b)(1)(B)(i), as applied to these facts, is not faithful to the plain meaning and purpose of the statute.⁸ Put simply, in computing "time consumed by continued examination," the PTO should not include time when the PTO was plainly not conducting continued

⁸ ARIAD argues in the alternative that the PTO should have applied 37 C.F.R. § 1.183, which enables the PTO Director to suspend or waive "[i]n an extraordinary situation, when justice requires, . . . any requirement of the regulations in this part which is not a requirement of the statutes" It is not necessary to consider the applicability of 37 C.F.R. § 1.183 where, as here, the PTO's interpretation of the statute is inconsistent with Congress's clear intent. But it is important to note that the PTO could have avoided this litigation had it considered the three-month erroneous abandonment of ARIAD's application owing entirely to a mistake by the PTO to be an "extraordinary situation" warranting suspension of its regulations.

examination, but instead negligently concluded that the patent application had been abandoned.

Thus, plaintiff is entitled to judgment as a matter of law.

An appropriate order will issue.

Alexandria, Virginia January 5, 2018

T. S. Ellis, III

United States District Judge